SHPA submission to the Health Technology Assessment (HTA) Policy and Methods Review - consultation 1, June 2023

Introduction

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation representing the over 6,100 Hospital Pharmacists, their hospital pharmacy interns and hospital pharmacy technicians working across Australia's hospitals and healthcare system. SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care. SHPA is committed to facilitating safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

SHPA welcomes the opportunity to provide input into the independent review of Australia's Health Technology Assessment (HTA) Policy and Methods. After the long-awaited review of Australia's National Medicines Policy (NMP), the updated document published in 2022 affirmed the Australian Government's priority to resource equitable and affordable medication access and care that meets patient need, regardless of location or care setting.

SHPA also notes the HTA review's context and timing with recent reviews of the Section 100 Efficient Funding of Chemotherapy (EFC) program, the Pharmaceutical Reform Agreement (PRA), and the concurrent review into the National Health Reform Agreement (NHRA), as a crucial opportunity to correct policy settings for medicines access in hospital settings as fit-for-purpose and achieving the needs and expectations of patients. SHPA's full submissions containing several recommendations to each of the recent reviews are linked below for reference:

- SHPA submission to National Medicines Policy (NMP)
- SHPA submission to Section 100 Efficient Funding of Chemotherapy (EFC)
- SHPA submission to Pharmaceutical Reform Agreements (PRA)

Hospital pharmacists as medicines experts operationally manage and clinically ensure the safe, efficient and effective use of medicines within Australia's hospital system. Hospital pharmacists are responsible for almost a quarter of all Pharmaceutical Benefits Scheme (PBS) medicines expenditure, accounting for just over $3 billion in expenditure from public and private hospitals each year when providing care and supplying medicines to hospital patients.

In this submission, SHPA makes a range of recommendations to improve the HTA policy and methods to support early, equitable, and person-centred quality use of medicines for all Australians, particularly those most unwell and receiving treatment in the acute care setting.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

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SHPA's Recommendations to the HTA Policy and Methods Review

Recommendation 1: Develop a single-funder model for health technologies provided in hospitals to facilitate early and equitable access to high-cost and complex medications.

Recommendation 2: Enable public hospital pharmacies to supply PBS-subsidised medicines for public hospital inpatients to achieve equity and enhance quality use of medicines and medicines safety.

Recommendation 3: Funding pathways must consider the whole cost of therapy, including ancillary services, to support early and equitable access to health technologies across Australian hospitals.

Recommendation 4: Registration and reimbursement decisions should consider the use of a health technology in the acute care setting to facilitate early and equitable access to patients in Australian hospitals.

Recommendation 5: Develop a repository of non-PBS, off-label and Special Access Scheme (SAS) medicines data gathered from all hospitals across Australia to facilitate more timely decision making and provide Australians with early access to medicines needed in the acute care setting.

Recommendation 6: Enable hospital pharmacists to supply medicines to Indigenous Australians under Closing the Gap PBS Co-Payment Measure.

Recommendation 7: Address cost and time barriers prohibiting sponsors of generic medicines from applying for HTAs to expedite access to health technologies in Australia.

Recommendation 8: Funding pathways for medicines used in hospitals should account for innovative, patient-centred models of care aiming to provide care to patients where they wish to receive it, without compromising medicines access and quality use of medicines.

Recommendation 9: Establish a nationally coordinated and systematic process for identifying and monitoring emerging technologies relevant to the acute care setting.

Recommendation 10: Develop funding pathways to support the equitable delivery of innovative treatment with precision medicine to deliver personalised healthcare and better treatment options for Australians.

Recommendation 11: Collect data on the use of non-PBS medicines across all care settings, including the use of unregistered medicines and off-label medicines, to inform future funding decisions, policies, regulations and clinical guidelines preventing future medicine-related hospital admissions.

Elements and features that are working effectively

1. Are there any elements and features of HTA policy and methods in Australia that are working effectively?

Yes - there are elements and features of HTA policy and methods in Australia that are working effectively and should not change.

2. Are you able to provide detail of any elements and features of HTA policy and methods that are working effectively? Please use specific details where possible.

The HTA policy and methods has for years provided Australians with safe and affordable access to health technologies that support improved health outcomes. The hospital pharmacy sector has high regard for the independence of the process and the committees involved, and for the stringent and rigorous HTA policy and methods used to scrutinise applications for health technologies in Australia. Applying an evidence-based approach to assessments is essential to securing the safety of Australians and access to quality care. However, there are major gaps in the current HTA policy and methods that impede on early, equitable and person-centred access to new health technologies that must be addressed as a matter of urgency.

Whilst advancements in the health technologies landscape are burgeoning rapidly, and it is anticipated that new methods for evaluating emerging technologies and new funding pathways may be outcomes of this Review, the current HTA policy and methods has at times shown consideration of the broader implications of a health technology on the health system.

Examples:

- Highly specialised therapies and their associated ancillary services are jointly funded by the Australian Government and all states and territories under the National Health Reform Agreement (NHRA), supporting national access to treatment for patients with rare conditions. Some of these therapies funded under the NHRA include:
    - Chimeric Antigen Receptor Therapies (CAR-T) cell therapy, tisagenlecleucel (Kymriah) for the treatment of paediatric and adolescent Acute Lymphoblastic Leukaemia (ALL), and adult relapsed or refractory diffuse large B cell lymphoma (DLBCL)
    - CAR-T cell therapy, axicabtagene ciloleucel (Yescarta), for the treatment of adult relapsed or refractory large B-cell lymphoma, and paediatric and adolescents with B-cell precursor ALL
    - Gene therapy, voretigene neparvovec-rzyl (Luxturna), for the treatment of inherited retinal dystrophies
    - Immunotherapy, dinutuximab beta (Qarziba), for the treatment of high-risk neuroblastoma
- Emicizumab (Hemlibra) used for the treatment for haemophilia, is available to eligible patients free of charge through the National Blood Authority (NBA), which is jointly funded by the Australian Government and all states and territories
- Eculizumab (Soliris) prescribed for the treatment of Paroxysmal Nocturnal Haemoglobinuria (PNH) previously subsidised under the Life Saving Drugs Program, is currently listed on the PBS and is available under the Section 100 Highly Specialised Drugs (HSD) program

More and more therapies are proving to require complex administration and will not neatly fit into the PBS funding model in its current form if we are to ensure person-centred and equitable access to health technologies, as outlined in the NMP.

3. **Are you able to provide details of positive outcomes resulting from Australia's HTA policies and methods? Please use specific examples where possible.**

As discussed, when the HTA has been successful at considering the broader implications of a health technology on the health system, it has been able to make funding recommendations that better align with patient needs ensuring they have access to the health technology they need, when and where they need it.

Example:

- As mentioned above, the current funding arrangement for emicizumab (Hemlibra) for the treatment for haemophilia under the NBA, allows prompt initiation of therapy in the inpatient setting for critically unwell patients, including in Intensive Care Unit (ICU) settings

Current or future barriers to earliest possible access

4. **What are the elements and features of HTA policy and methods that are acting as a *current* barrier to earliest possible access?**

Lack of coordination within Government/s

The Australian Government's system for providing access to health technologies is complex and inefficient. Whilst SHPA recognises that each part of the system is unique and plays a crucial role in the assessment process, there is a significant amount of overlap that leads to delays in access;

- the Therapeutic Goods Administration (TGA) is responsible for the market authorisation process, evaluating and assessing a range of criteria including the **safety** and efficacy of new health technologies, and entering approved therapeutic goods on the Australian Register of Therapeutic Goods (ARTG)
- the Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC) are responsible for making recommendations to government on approved products/services to be considered for listing on relevant Australian subsidy programs, and assess a range of elements including **clinical effectiveness**, **safety,** and cost-effectiveness
- Drug Therapeutic Committees (DTCs) or equivalent, responsible for the overall governance of the medicines management system in their health service organisation, assess a range of criteria including the **safety**, quality, **clinical effectiveness,** and cost-effectiveness of medicines

The safety of a health technology is assessed at all three stages of the approval pathway before it is available for use in hospitals. The clinical effectiveness of a health technology is assessed by both PBAC/MSAC and DTCs before being available for use in hospitals. These elements of the assessment pathway should not yield varied results when undertaken by different arms of the system with varied purposes i.e., if a health technology is deemed safe by the TGA, it should be deemed safe by PBAC/MSAC and by hospital DTCs, just as a health technology deemed to be clinically effective by PBAC/MSAC for use in a particular condition should be deemed clinically effective by hospital DTCs if assessing for the same condition.

It is, however, appreciated that other criteria, although assessed by multiple bodies, may yield varied outcomes as it is being viewed through different lenses i.e., cost-effectiveness is assessed by both PBAC/MSAC and DTCs, however what may seem cost-effective from PBAC/MSAC viewpoint, may not be when assessed by DTCs for an acute setting with a specific demographic.

Fundamentally, there is a need for a more coordinated approach to health technology assessments to streamline these processes and provide Australians with earlier access to health technologies. A single-funder model for health technologies utilised in hospitals, is recommended to eliminate unnecessary duplication and support early access to medicines in the acute care setting.

Lack of consultation with the acute care sector during the HTA process

The current HTA process does not allow for sufficient consultation with stakeholders in the acute care sector who have a significant role in the funding, delivery, prescribing, supplying, and administration of these health technologies. The acute and highly specialised nature of hospitals means that their utilisation of health technologies is often vastly different from that of the primary care setting.

Hospitals provide care to the most unwell patients who may have exhausted conventional first and second-line therapies, thus requiring the use of off-label medications and medications that are not registered in Australia. Hospital pharmacists have vast experience with off-label and Special Access Scheme (SAS) medicines and acknowledge that it is poorly understood by clinicians and patients. The lack of regulatory approval for these indications impacts on clinician confidence and ability to safely provide evidence-based and transparent care. SHPA's Medicines Information Leadership Committee state that approximately two-thirds of all medicines information inquiries they receive in hospitals are in relation to the off-label use of medicines.

Where appropriate, Australia should make greater use of international approval processes. Product information and evidence available for medications approved overseas for indications that are yet to be approved by the TGA, should be accepted as evidence in a sponsor's application. This would significantly reduce the regulatory burden on sponsors seeking to apply for expanded indication and enhance early access to these health technologies. Expanding the regulatory approval of these medicines would be of great benefit to clinicians and patients, and would ensure medicines are being used more appropriately where indicated. It will also alleviate practitioner concerns and allow patients to be more informed and involved with their healthcare.

Hospitals should also be engaged and offered an opportunity to provide clinical input into PBS indications for conditions relevant to the acute sector. Fundamentally, PBAC's recommendation to government to subsidise a health technology through the PBS does not amount to much if the setting in which this health technology is to be used is not ready, willing, or resourced to deliver it. The lack of preparedness of the acute sector to deliver certain high-cost therapies inhibits earliest possible access to health technologies. It is for this reason that it may take years before a medicine listed on the PBS is added to a hospital formulary and available to patients in the acute care setting. As part of the assessment process, HTAs should undertake an impact assessment reviewing the capacity of the healthcare system, particularly the hospital sector, to deliver the health technology being assessed.

Cost and time associated with HTAs and low revenue for sponsors

As Australia comprises less than 2% of the global pharmaceutical market, the cost and complexity associated with placing applications for assessment of new health technologies by international sponsors is currently a significant barrier to early access to new therapies. This is especially relevant to health technologies for the treatment of rare diseases or minority populations such as children, as highlighted in the report delivered by the House of Representatives Standing Committee on Health, Aged Care and Sport in November 2021 titled *The New Frontier – Delivering better health for all Australians*[1], in response to the Inquiry into approval processes for new drugs and novel medical technologies in Australia. These factors become more problematic when multiple resubmissions are required for a single health technology to receive a positive recommendation from the review committee. Clearer direction to sponsors on what specific data PBAC/MSAC are seeking could encourage sponsors to apply for HTAs in Australia and facilitate early access to these health technologies as sponsors would only provide targeted data rather than copious amounts of unnecessary information.

Cost and time associated with HTAs are also a barrier for sponsors of new generic versions of medications bringing their products into the Australian market and/or investing in Australia's medicine industry.

Prioritisation of the evaluation of first and second generic versions of innovator medicines would assist in preventing medicine shortages. This will allow for faster market access for medicines for which there is currently no alternative brand on the ARTG. Waiving application and/or evaluation fees for new generic versions of medicines known to often be in shortage or limited supply may also encourage suppliers of generic medicines to bring their products into the Australian market and/or invest in Australia's medicine industry. This would improve access to medicines that are often in shortage and assist in preventing future shortages.

Many low-cost medicines that do not have patent protection are commonly used as off-label for unapproved indications due to the prohibitive costs of HTAs in Australia and the anticipated low revenue for sponsors.

Example:

- Domperidone is used off-label to treat lactation insufficiency. Despite holding regulatory approval for this indication by a reputable overseas medicines regulator, the low-cost and lack of market exclusivity for this medicine provides little incentive for it's sponsor to submit an application to the TGA for expanded indications.

As discussed earlier, the Australian government should make greater use of international approval processes to reduce the prohibitive costs and time associated with HTAs in Australia. Where there is product information and evidence available for medicines approved overseas for indications that are yet to be approved by the TGA, these should be accepted as evidence in a sponsor's application. This would significantly reduce the regulatory burden on sponsors seeking to apply for expanded indications and expediate access to health technologies in Australia.

Evidence required for HTA

The need for a robust evidence base is essential when assessing the quality and safety of a health technology, however, it can at times prove to be a barrier to early access of therapies especially to minority populations or for the treatment of rare diseases, since the data is often insufficient. Limited clinical data in these cases should not be used as a tool to negotiate the lowest price possible. Given our small global pharmaceutical market share, we should not be discouraging sponsors of health technologies that treat rare diseases or minority populations form investing in Australia by driving down the prices and value of their products.

Examples:

- Medications for the management of cystic fibrosis in children. HTA parameters for assessing the evidence of health technologies such as these should be adjusted to accommodate the lower volume of patients involved in clinical trials, and the complexities with obtaining ethics approvals for conducting clinical trials on children.

Treatment for minority populations and rare diseases that require the use of non-PBS and off-label medicines and medicines that are not registered in Australia, is often provided or initiated in a hospital setting. There is significant crossover between what would be considered off-label and off-formulary in a hospital.

When hospital pharmacists or prescribers require the use of a medicine that is not on the hospital formulary, typically they will need to make an Individual Patient Usage (IPU) application that is reviewed by the Hospital DTCs, that evaluates the literature for the indication that it is meant to treat, what the treatment success markers are, and the projected costs to allow for a cost-efficiency analysis. IPUs that are approved by the DTCs require regular reporting by the applying prescriber on the patients' prognosis and measurement of the identified treatment success markers, to make the case for continued approval of the IPU.

IPU datasets held by individual hospitals and hospital networks are a critical and untapped database that would likely have a wealth of independent clinical evidence and information to assist with the identification of

medications for registration in Australia. The Australian government in collaboration with state and territory governments should develop a repository of non-PBS, off-label and Special Access Scheme (SAS) medicine data gathered from all hospitals across Australia. This data sharing measure would support more timely decision making and provide Australians with early access to medicines needed in the acute care setting.

Hospital pharmacists are well placed to tap into this resource and utilising their own clinical experience treating patients with non-PBS, off-label and Special Access Scheme (SAS) medicines, provide reliable information to the Australian government on medicines that need to be registered for local use. SHPA is the ideal conduit between hospital pharmacists and the Australian Government through the 30+ speciality practice groups we convene of pharmacists with specialised expertise in various therapeutic areas.

Exorbitant fees for non-pharmaceutical industry groups to sponsor an HTA application

Given the range of factors discussed earlier, that may make certain sponsors reluctant to apply to the PBAC for subsidy of their health technology, establishing a fund to support health professionals, peak bodies and consumer groups to sponsor a registration and reimbursement applications for certain health technologies, would facilitate early access to medicines. This aligns with Recommendation 9 of *The New Frontier – Delivering better health for all Australians*[1] report.

5. What are the elements and features of HTA policy and methods that may act as a *future* barrier to earliest possible access?

Horizon scanning

There is a need for a nationally coordinated and systematic process of identifying and monitoring emerging technologies that have the potential to significantly impact the acute care sector. A coordinated approach allows the Australian hospital system to stay ahead of the curve and plan for the adoption and integration of these technologies into clinical practice.

A nationally coordinated approach also encourages collaboration and the sharing of knowledge among healthcare organisations, policymakers, researchers, and professional organisations. This pooling of expertise, resources, and information, fosters a more comprehensive understanding of emerging technologies most relevant to the Australian healthcare landscape and their implications. It also highlights potential gaps in the regulatory framework, providing policymakers with an opportunity to proactively address these issues, ensuring that the regulatory environment keeps pace with technological advancements. As stated earlier, a national repository of clinical data on non-PBS and unapproved medicines used in hospital setting would be a useful resource to leverage off the experience of specialist clinicians and pharmacists, and a means of scanning the horizon for medicines commonly used in the acute care setting, to be considered for approval in Australia.

SHPA annually publishes *Pharmacy Forecast Australia,* a strategic thought leadership piece on emerging trends and phenomena projected to impact pharmacy practice and the health of Australian patients over the ensuing five years. Utilising ‘wisdom of crowds’ methodology, Pharmacy Forecast Australia surveys leading pharmacists with expertise in health-system pharmacy, knowledge of trends and new developments in the field, and the ability to think analytically about the future hospital pharmacy leaders. Pharmacy Forecast Australia is a stimulant to prompt discussion that assists health system leaders in their strategic planning efforts and in their mission to provide optimal care for patients and advancing the profession of pharmacy.

SHPA would welcome the opportunity to partner with government to expand the current forecasting activities to better prepare the Australian hospital system for emerging health technologies.

Sovereign capability to undertake clinical trials

Australia must seek to increase its capacity for clinical trials by funding more research and improving the clinical trials workforce in Australia. Hospitals and other healthcare agencies are the major centres for clinical

trials with investigational products and according to SHPA's *Standard of practice in clinical trials for pharmacy services*, pharmacists in these institutions are involved with policies and procedures for the safe and ethical use of investigational products. A stronger clinical trials workforce is necessary to maximise Australia's capacity to undertake clinical trials and improve the rate at which they are being opened and closed.

Funding is required to improve research of new medications and novel medical technologies in Australia. As demonstrated by the recent COVID-19 pandemic, there is a need for Australia to have a dynamic and responsive clinical trials environment to support the development of new medications at the time they are needed. SHPA is a great advocate for research of medications, with a dedicated Research speciality practice stream comprised of research pharmacists, and a leading research journal *'Journal of Pharmacy Practice and Research (JPPR).'* SHPA also has a starter kit to support pharmacists wishing to embark on research, and funds research grants, practitioner grants and educational grants to support members in furthering research in their specialised fields of practice.

6. Would you like to provide feasible options or suggestions you have to improve elements of HTA policy and methods that are acting as a current or future barrier to earliest possible access?

Recommendation 1: Develop a single-funder model for health technologies provided in hospitals to facilitate early and equitable access to high-cost and complex medications.
Recommendation 5: Develop a repository of non-PBS, off-label and Special Access Scheme (SAS) medicines data gathered from all hospitals across Australia to facilitate more timely decision making and provide Australians with early access to medicines needed in the acute care setting.
Recommendation 4: Registration and reimbursement decisions should consider the use of a health technology in the acute care setting to facilitate early and equitable access to patients in Australian hospitals.
Recommendation 7: Address cost and time barriers prohibiting sponsors of generic medicines from applying for HTAs to expediate access to health technologies in Australia.
Recommendation 9: Establish a nationally coordinated and systematic process for identifying and monitoring emerging technologies relevant to the acute care setting.

Current or future barriers to equitable access

7. What are the elements and features of HTA policy and methods that are acting as a current or future barrier to equitable access?

As mentioned in the introduction, other significant reviews have taken place over the past year that impact on equitable access to medicines in Australia. Both the Section 100 EFC and PRA are essential for attempts by hospitals and hospital pharmacists to facilitate equitable, timely and affordable access to medicines subsidised on the PBS for cancer patients, and hospital patients receiving medicines upon discharge or from outpatient clinics. Since Section 100 EFC and PRAs have been enabled throughout most jurisdictions, hospital pharmacists have never been provided appropriate or equitable remuneration compared to community pharmacists for supplying the same PBS medicines. Furthermore, access to the PBS medicines and non-PBS medicines is variable across hospitals due to confounding factors which are explored further below.

Lack of PBS funding for hospital inpatients

One of the purposes of HTAs is to assist and inform government funding decisions to support timely access to health technologies when and where patients need them. Medicines approved by the HTA system have generally been subsidised through the PBS. The PBS aims to provide timely, reliable and affordable access to necessary medicines for Australians in line with the central pillars and the principle of equity in the NMP.

Since the commencement of PRAs there have been calls for PBS funding of medications to extend to all care settings, including private and public hospital inpatients in addition to day-admitted and outpatients. However, over 20 years later, these arrangements continue to be limited to specific patient groups and care settings.

In contrast, over this same time period, the definition of a hospital inpatient has evolved. Most states now offer Hospital in the Home, simultaneously described as "admitted care in the comfort of the patient's home" and "an alternative to an inpatient stay."[2] Hospital in the Home programs attract Activity-Based Funding but create a blurred line for funding of pharmaceuticals used by patients in their own home (including regular medications).

The development of newer models of care has been accelerated by the COVID-19 pandemic, including hospital-initiated community in-reach/outreach services. The adoption of telehealth has likewise been advanced, with TeleChemotherapy services in WA and Virtual Clinical Pharmacy services in NSW and Tasmania. These models make it clear that the boundaries between the patient, the care provider(s) and their physical location are no longer relevant to the process of care delivery. Despite this, these factors play a key determinant in access to subsidised funding, as noted in the review of PBS Pharmaceuticals in Hospitals.[3]

Public hospitals are sometimes unable to fund treatment for expensive medicines for inpatients without PBS support. This is often problematic for drugs that require hospitalisation as part of the treatment, highlighting a tension emblematic of historical federal-state funding conflicts.[4]

Examples:

- Blinatumomab is a PBS subsidised immunotherapy that must be initiated during a hospital admission, as highlighted in the PBS authority criteria. The TGA-approved product information states that hospitalisation is required for the first nine days of the first cycle and the first two days of subsequent cycles. Ironically, however, the PBS authority criteria also notes that this medicine cannot be subsidised if administered to an inpatient in a public hospital setting. The cost of delivering this medicine and the hospital admission can be very expensive meaning not all hospitals can afford to deliver this therapy to their patients, creating inequity in access
- Clinicians at times delay treatment with important medicines such as iron infusions, depot injections for schizophrenia, and oral chemotherapy for inpatients until after discharge where patients are then referred to outpatient or general practice (GP) clinics to access subsidised medicines through the PBS. Not only is this inequitable, inefficient, and delays necessary healthcare, it relies on patients who are recovering from an acute medical event, to make an appointment and present to an outpatient clinic or to their GP to receive necessary, and at times lifesaving medicines. Research shows that over a quarter of patients fail to make it to a local pharmacy until days after discharge to have their discharge prescription dispensed.[5] This poses a significant health risk to patients and at times results in hospital readmissions.

The lack of PBS funding for public hospital inpatients also causes issues for patients admitted to hospitals who are taking high-cost medicines in the community that are listed under Section 100 Highly Specialised Drugs (HSD) or are high-cost Section 85 medicines. If they present to hospital without their regular medicines, which is often the case due to unplanned hospital admissions, then public hospitals are put in a position where they may need to open a PBS pack of very high-cost medicines such as medicines for cystic fibrosis or oral chemotherapy, to ensure continuation of therapy in hospital.

This is extremely inefficient and expensive for public hospitals, and in many instances, these vital medicines are not provided at all until a carer can bring in their PBS-dispensed pack from home, which does not always occur. Once a PBS pack is opened, remaining dosages cannot be resupplied to another patient, and has a major risk of eventually expiring and having to be wasted. This is just another unintended consequence of this inequity that can be rectified by allowing public hospital inpatient access to PBS-subsidised medicines.

The lack of uniform access to the PBS also affects equity of treatment and outcomes, even among states that are signatories to Pharmaceutical Reforms. Access to the PBS for private hospital inpatients means some patients will have access to medicines that are not available in a neighbouring public hospital.[6] These issues are further compounded by the federated approach to hospital funding, medicines formularies and funding.[7]

SHPA strongly advocates for the extension of the PBS to cover all hospital medications which has been identified by the National Centre for Social and Economic Modelling as a key measure that would increase equity of access, remove incentives for cost shifting, and better meet the needs of patients.[8]

Lack of funding pathways for high-cost medicines in hospitals that account for the whole cost of therapy

Rapidly evolving treatment options which have changed the profile of new medicines being brought to market, have increasingly highlighted issues around access and equity. Twenty years ago new medicines were predominantly small molecules for lifestyle-related non-communicable diseases. In recent years, advancements in health technology and research have seen more complex and high-cost medicines being brought to market to treat diseases requiring acute hospital or outpatient care, such as cancers, autoimmune diseases and genetic diseases.

Public hospitals and hospital pharmacy departments play a crucial role in access to novel, usually high-cost and/or off-label medicines to treat complex and uncommon diseases before these medicines are registered on the ARTG and well before they are listed on the PBS. They are also integral to patient access to clinical trials. According to the Council of Australian Therapeutic Advisory Groups (CATAG), virtually all therapeutically complex and/or new drugs are first used in hospitals, with 73% used in public hospitals.

Due to the complex and specialised nature of these medicines, as well as their cost, patient access to these medicines differs greatly between hospital networks and between jurisdictions. They are subject to various factors including:

- fixed hospital pharmaceutical budget constraints
- varying access to compassionate access schemes
- local Drug and Therapeutic Committee policies and decisions
- access to specialist clinicians
- proximity to large hospitals
- varying out-of-pocket expenses determined by local and jurisdictional policies

More recently, limitations have been applied to the use of PBS in public hospitals for high-cost medicines requiring initiation in the inpatient hospital setting, potentially resulting in inequity of consumer access.[9]

Examples:

- Nusinersen is PBS subsidised medication used to treat spinal muscular atrophy in children, however if a child has scoliosis, they are administered this medication under general anaesthetic with guided imaging and require a hospital admission for a day or two for recovery. In this case, the cost of the anaesthetic, the staff required to administer the medication, and the additional hospital admission, is not meaningfully recognised by hospital funding mechanisms such as activity based funding
- The active agent in some chemotherapy preparations is subsidised via the PBS however the cost of the infusion fluid, excipients and the administration aids necessary are not. This adds a significant layer of complexity for hospitals and patients in fee arrangements given the use of both PBS and non-PBS medicines.

The lack of suitable funding pathways that provide subsidy for the whole cost of therapy, including ancillary services, drive inequity in access as not all hospital budgets are able to absorb these additional costs and therefore access becomes a matter of postcode lottery.

Significant structural reform is required to ensure medicines funding mechanisms in Australia remain fit for purpose and sustainable. Development of single-funder models for medicines in hospitals will reduce inequity of patient access to high-cost and complex medicines, and enable patient-centred and timely provision of treatment when and where patients require them, aligning with Australia's National Medicines Policy.[10]

Reliability of sponsor/manufacturers of health technologies

HTA processes in place to ensure a sponsor is able to meet the supply needs of the population before receiving subsidy, are not sufficient as medicine shortages continues to be a major issue impacting hospitals in Australia. Medicine shortages have resulted in delays to treatment and less effective medicines being utilised, all of which potentially contribute to prolonged hospital inpatient admissions. Shortages and interruptions in supply have increased procurement costs to hospital pharmacy departments.

A sponsor's reliability in producing sufficient stock is essential in achieving equitable access to medicines for all Australians who require it.

Funding pathways for evolving innovative approaches to treatment

Over 50% of pharmacy leaders who provided input into SHPA's Pharmacy Forecast 2022[11], believe that hospital pharmacy departments will look to have precision medicine in hospitals within the next five years. It is imperative that Australia begins to develop policies and regulations that support the safe use of precision medicine. Suitable funding pathways to support the equitable delivery of innovative treatment with precision medicine must be considered to ensure Australia remains at the forefront of this field, providing personalised healthcare and better treatment options for its population.

8. Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are acting as a current or future barrier to equitable access?

Recommendation 1: Develop a single-funder model for health technologies provided in hospitals to provide early and equitable access to high-cost and complex medications.
Recommendation 2: Enable public hospital pharmacies to supply PBS-subsidised medicines for public hospital inpatients to achieve equity and enhance quality use of medicines and medicines safety.
Recommendation 3: Funding pathways must consider the whole cost of therapy, including ancillary services, to support early and equitable access to health technologies across Australian hospitals.
Recommendation 10: Develop funding pathways to support the equitable delivery of innovative treatment with precision medicine to deliver personalised healthcare and better treatment options for Australians.

Elements and features that detract from person centeredness

9. Are you able to provide details of any elements and features of HTA policy and methods that may be detracting from person-centeredness?

PBS restrictions

The PBS prescribing restrictions do not at times match clinical guidelines, and in instances where they do, they often do not accommodate the use of these medicines in an acute setting. The hospital setting treats patients who are more acutely unwell and require a different level of care to those in the community. PBS restrictions for some health technologies are approved by PBAC under specific clinical guidelines more commonly relevant to treatment in the primary care setting. These medicines are used differently in hospital practice i.e., different doses, alternate route of administration, to treat different conditions. This variation can create a misalignment between the PBS restrictions on clinical guidelines and prescribing in hospitals. In other instances, PBS restrictions provide subsidy for use in a certain condition but not in another, although indicated per clinical guidelines. A person-centred approach to medicine subsidy means PBS restrictions

should encompass evidence-based clinical practice in the acute care setting as well as in the primary care setting.

Examples:

- PBS criteria for antivirals used in the treatment of COVID-19 do not align with the national COVID-19 guidelines developed by the National COVID-19 Clinical Evidence Taskforce, of which SHPA is a member
- Shingrix is a vaccination for shingles and is subsidised for bone marrow transplant patients however not subsidised for other transplant patients who also require its use, creating inequity in access

Arbitrary funding rules impact delivery of person-centred care

The Closing the Gap (CTG) PBS Co-payment Program designed to help Aboriginal and Torres Strait Islander Australians access low cost or free PBS medicines, currently excludes medicines dispensed at discharge from public hospitals. The requirement for a co-payment to receive medicines at discharge from a public hospital, has resulted in ongoing inequity in the provision of medications. Without access to the Program, individual hospital policies (which require a co-payment as specified by PBS procedures) often prevent Indigenous patients from receiving their medicines at discharge to avoid incurring operational cost. If patients are unable or unwilling to pay the co-payment, they must attend a community pharmacy post-discharge to receive discharge medicines. A person-centred approach would ensure that Aboriginal and Torres Strait Islander people could access the Program designed to support their adherence to medicines, wherever and whenever they need it.

Proactive measures to facilitate a person-centred approach to affordable medicines

As discussed above, prioritisation of the evaluation of first and second generic versions of innovator medicines, and the waiving of applications and/or evaluation fees for these medicines is a person-centred approach to preventing medicine shortages. Similarly, PBAC has a role in making recommendations to government to subsidise alternative medicines to those experiencing extended shortages to ensure Australians continue to have access to affordable medicines when they require them.

Example:

- There is currently an extended shortage of metoclopramide hydrochloride monohydrate (Maxolon) 10mg/2mL injection ampoules commonly used to treat nausea and vomiting in patients with cancer and in palliative care. Whilst there are another two brands of metoclopramide, this is the only brand listed on the PBS. Patients who are acutely unwell have to resort to non-PBS subsidised brands of metoclopramide until Maxolon becomes available again.

Development of funding pathways that support person-centred care

HTA funding pathways should also acknowledge that the patient journey is no longer a simple pathway back and forth between hospital and community settings, and should be updated to enable quality access to medicines and pharmacy services in all the innovative models of care. Some examples are:

- Hospital in the home
- Hospital in the nursing home
- Pharmacist-led outpatient clinics
- Aged care outreach programs
- Post-discharge programs to prevent re-admission
- Models of care necessitated by COVID-19 pandemic
- Virtual care models, telehealth models
- District nursing services, community health services and Primary Health Networks

As discussed earlier, the exclusion of public hospital inpatients from accessing PBS-subsidised medicines, but enabling outpatient access and access upon discharge, has become increasingly not fit-for-purpose and fails to address contemporary needs as hospital care and delivery can no longer be simplified to the inpatient/outpatient binary. Rather, hospital and hospital pharmacy care have the flexibility to be delivered to patients in the setting and circumstances most appropriate to them, enabling a patient-centred approach. Commensurate support from funding pathways is required to maximise the benefits of subsidised medicines ensuring they are delivered in a safe manner across all settings.

Improved data collection and analysis to support person-centred care

At present, data on PBS medicines use is systematically collected by Services Australia and the Department of Health, however there is no data collection on non-PBS medicines use in all settings of care, including the use of unregistered medicines and off-label medicines.

Data relating to medicine-related outcomes is also not collected systematically, with key statistics such as the 250,000 medicine-related hospital admissions annually being pieced together by an extensive literature review. The reporting of adverse events caused by medicines is undertaken on a voluntary basis. For hospital pharmacists, when adverse events are reported, this often requires a duplication of the same report to both the TGA as well as local incident management reporting systems, which may then be further examined by state governments.

The systematic collection of this significant information is a person-centred measure to inform future funding decisions of non-PBS medicines commonly used, and policies, regulations and clinical guidelines to prevent future medicine-related hospital admissions.

10. Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are detracting from person-centeredness?

Recommendation 4: Registration and reimbursement decisions should consider the use of a health technology in the acute care setting to facilitate early and equitable access to patients in Australian hospitals.
Recommendation 6: Enable hospital pharmacists to supply medicines to Indigenous Australians under Closing the Gap PBS Co-Payment Measure.
Recommendation 7: Address cost and time barriers prohibiting sponsors of generic medicines from applying for HTAs to expediate access to health technologies in Australia.
Recommendation 8: Funding pathways for medicines used in hospitals should account for innovative, patient-centred models of care aiming to provide care to patients where they wish to receive it, without compromising medicines access and quality use of medicines.
Recommendation 11: Collect data on the use of non-PBS medicines across all care settings, including the use of unregistered medicines and off-label medicines, to inform future funding decisions, policies, regulations and clinical guidelines preventing future medicine-related hospital admissions.

Perverse incentives

11. Are you able to provide details of elements of features of HTA policy and methods that are causing or could cause unintended consequence or perverse incentives?

Lack of access to PBS subsidised medicines for hospital inpatients

The lack of access to PBS subsidised medicines for public hospital inpatients results in cost shifting incentives remaining at the expense of efficient, quality and safe healthcare delivery and impacting patient healthcare outcomes. Without PBS subsidy for public hospital inpatients, there are perverse incentives to delay initiation of certain higher cost treatments until the point of discharge to access PBS subsidy, such as antipsychotic depot injections, iron infusions, Hepatitis C medications, infusions for osteoporosis, and cancer therapy. In some cases, patients are provided outpatient prescriptions for high-cost medicines to be

dispensed under the PBS in the community, and bring it to the hospital for administration as an inpatient. These arbitrary funding rules present clinicians with challenging ethical dilemmas as they endeavour to provide their patients with the best possible and affordable access to life-saving medicines.

Increasing frequency of hospital outpatient appointments

Incentive to claim for an episode of care each time a patient attends an outpatient appointment can at times be a perverse incentive to increase the frequency that that patient must present to receive treatment, although it may not always be necessary. Certain formulations of medicines that require administration in outpatient clinics, are at times prescribed over other more convenient formulations that can be self-administered at home to ensure clinics can continue to claim episodes of care.

Examples:

- Patients requiring methotrexate to treat rheumatoid arthritis or psoriasis, for whom the oral tablet formulation is unsuitable, can often be prescribed methotrexate pre-filled syringes, however some of these patients are prescribed other parenteral formulations to ensure they continue to attend the outpatient clinic
- Ocrelizumab and natalizumab used to treat multiple sclerosis are intravenous formulations often prescribed for patients whilst ofatumumab, a subcutaneous formulation also used to treat multiple sclerosis is available for self-administration

12. Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are creating unintended outcomes or perverse incentives either currently or in the future?

Recommendation 2: Enable public hospital pharmacies to supply PBS-subsidised medicines for public hospital inpatients to achieve equity and enhance quality use of medicines and medicines safety.

Areas for further investigation or analysis

13. Details of: Which elements of the HTA policy, method, mechanism for suggested for consideration; Any outcomes that the suggestion is achieving that should be considered; Any unintended consequences that the suggestion is having or may have if adapted in Australia.

Redefining the ‘value’ of a health technology

Health technology assessments currently assess the comparative clinical and financial value of a health technology compared to other similar technologies available. There is a need to redefine ‘value’ and for the TGA and, PBAC and MSAC to examine the clinical, social, and financial value of approving or subsiding a health technology to enable access to patients requiring it, compared to *not* approving or subsidising it i.e., what are the implications of disease progression on a range of factors including, mental health, family life, loss of work, and hospitalisation. It is only when all these factors are considered that the value of a health technology can truly be measured, and approval or funding decisions be well informed.

Other details of importance to the HTA Policy and Methods Review not covered above

14. Noting the objectives of the review set out in the Terms of Reference, is there any other information relevant to the Review not provided above that you would like to add?

Disinvestment in health technologies that are not fit-for-purpose

Acknowledging that the Australian government is working to provide Australians with the best possible access to health technologies within the constraints of a finite budget, there is a need to formalise the process of disinvesting in health technologies that are no longer fit-for-purpose. PBAC and MSAC currently operate in a narrow remit, however, given their oversight over new and evolving health technologies, they are well placed

to make recommendations to government to disinvest in certain outdated health technologies that no longer meet contemporary efficiency parameters. This is money saving exercise means that more funding can be reinvested in newer and more valuable health technologies that better meet the healthcare needs of the Australian population. It is however important to ensure that if PBAC and MSAC expand their scope to include this function, that they are well resourced to do so efficiently and effectively.

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